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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/980,134   | 07/02/2002  | Raghuveer Basude     | DRE-0063            | 8214             |
| 26259  | 7590        | 05/13/2004           | EXAMINER            |                  |
| LICATLA & TYRRELL P.C.<br>66 E. MAIN STREET<br>MARLTON, NJ 08053 |             |                      | HARTLEY, MICHAEL G  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |

1616

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,134

Applicant(s)

BASUDE ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/12/02</u> . | 6) <input type="checkbox"/> Other: ____  |

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 10-14, the recitation of "objects" is indefinite because it is unclear what is encompassed by this term used herein. An "object" can be anything you can touch or see, as defined by the dictionary. However, it is unclear what all types of diverse objects are encompassed by the claims. The term object, as used herein, is not a term of art which would give it an understandable meaning to what would be encompassed or excluded thereby. Also, while gives a few examples, such as radioactive seeds or biopsy needles, the specification does not define the term object with any certainty to give an understanding of the metes and bound of this term.

These claims are further indefinite because they state that gas bubbles may encapsulate the object. It is unclear how gas bubbles could encapsulate biopsy needles.

Also, in these claims it is unclear what is meant by "an echogenic surface comprising an object" because it is unclear how the "surface" comprises an "object" or what the surface would encompass. An object has a surface, but a surface having an object is confusing. Also, since almost any object will have some degree of "echogenic" properties and it is unclear what types of surfaces would be within the scope thereof or what would be excluded. Also, since a surface is only part of an object, it is unclear how only the surface can be claimed as it is unclear what the surface is part of as a whole.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-7 and 10-14 rejected under 35 U.S.C. 102(b) as being anticipated by Rasor (US 5,141,738).

Rasor discloses a composition for ultrasound imaging comprising a microparticle having a hydrophobic surface (such as, a lipophilic surfactant) and a gas microbubble, see column 6, lines 3-11. The gas microbubble attaches or is contact with the microparticle, see column 6, line 57. The compositions are prepared by methods including storing the microparticle in a gaseous environment and introducing the microparticles into a liquid, see columns 9-10 and examples. The compositions contain a drug (which is also an object). Also, since the microparticle contains a lipophilic surface, it would have affinity for lipophilic gases such as perfluorocarbons that are somewhat lipophilic by nature.

Claims 1-7 and 9-14 rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (US 5,271,928).

Schneider discloses a composition for ultrasound imaging comprising a microparticle having a hydrophobic surface (such as, a liposome) and microbubbles which are associated therewith, in that the liposomes stabilize the microbubbles, see column 4, lines 6-36. The compositions are prepared by a method of storing the liposomes in a gaseous environment and introducing the liposomes into a liquid, see column 4, lines 37-55. The compositions may further include drugs, such as radionuclides for nuclear medicine, see column 10, lines 3-5, as well as, a targeting moiety, see column 9, lines 36-66. Also, since the microparticle contains a lipophilic surface, it would have affinity for lipophilic gases such as perfluorocarbons that are somewhat lipophilic by nature.

**NOTE:** The limitations in claims 2-5 and 10-14 are product-by-process limitations and the examination of such claims is based on the product itself. Since Rasor and Schneider disclose a product that is the same as claimed, these product-by-process limitations do not distinguish over the cited references.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor (5,141,738) or Schneider (5,271,928) in view of Unger (US 5,542,935).

Rasor and Schneider disclose compositions comprising a microparticle and microbubble for methods of ultrasound and/or drug delivery, as discussed above.

Rasor and Schneider fail to disclose that the methods of drug delivery include a step of insonating the desired site in the patient to rupture the microbubble thereby releasing a drug.

Unger discloses compositions comprising microbubbles that are useful for both ultrasound imaging and drug delivery, see abstract and column 35, lines 4-5. Unger teaches that the microbubbles may further comprise various drugs which are released by insonation to provide the advantage of site-specific delivery to a desired site, (e.g., the drug is not released until the particles reach the treatment site), see column 35, lines 29+.

It would have been obvious to one of ordinary skill in the art to use the compositions disclosed by Rasor or Schneider for drug delivery by insonating the microbubbles at a desired site *in vivo* because Unger teaches that analogous gas-filled microbubbles may further contain various drugs to yield a drug delivery means having the advantage of site-specific delivery by insonating the microbubbles at a desired site *in vivo*. One of ordinary skill in the art would have been motivated to employ the drug delivery methods disclosed by Unger using the compositions disclosed by Rasor and Schneider to obtain a composition which is useful for both ultrasound imaging and site-specific therapy using a single administration, wherein the insonating step provides release of the drug specifically at the treatment site.

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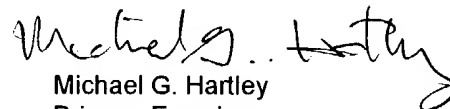
**Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

5/11/2004